

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 17, 2006.

The board will hold a public hearing starting at 3:00 p.m. on April 26, 2006 at the Red Lion Hotel, 1401 Arden Way, Sacramento, CA 95815, telephone (916) 922-8040. At the hearing any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The board requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 4005, 4007, 4038, 4115, and 4202 of the Business and Professions Code, and to implement, interpret or make specific Sections 4007, 4038, 4115 and 4202 of said Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4007 of the Business and Professions Code authorizes the board to adopt rules and regulations that may require a pharmacist to perform functions only under the effective supervision of a pharmacist who shall have the overall responsibility for supervising all activities that take place in the pharmacy.

Section 4029 of the Business and Professions Code defines "hospital pharmacy."

Section 4038 of the Business and Professions Code defines "pharmacy technician."

Section 4051 of the Business and Professions Code authorizes pharmacists to initiate a prescription and provide clinical advice or information or patient consultation when all of the following conditions are met: (1) the clinical advice or information or patient

consultation is provided to a health care professional or to a patient; (2) the pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice; and (3) access to the information described in (2) is secure from unauthorized access and use.

Section 4052 of the Business and Professions Code describes the functions a pharmacist is allowed to perform.

Section 4115 of the Business and Professions Code specifies the activities that may be preformed by a pharmacy technician.

Section 4202 of the Business and Professions Code specifies the requirements for becoming a licensed pharmacy technician.

Division 17, Title 16 of the California Code of Regulations, section 1793.7 describes the requirements for employing pharmacy technicians.

This proposed regulation of section 1793.8 will permit general acute care hospitals to employ specially trained pharmacy technicians in place of pharmacists to check the work of other pharmacy technicians filling floor stock, ward stock, and unit dose cassettes. Hospitals with a technician checking technician (TCT) program will be required to deploy pharmacists to the inpatient care setting to provide clinical services. Prior to initiating a TCT program, a general acute care hospital pharmacy will be required to have on file a description of the clinical pharmacy program.

To ensure quality patient care and reduce medications errors, the regulation will also require that a TCT program have the following components:

- The overall operation of the program shall be the responsibility of the pharmacist-in-charge.
- The program will be under the direct supervision of a pharmacist and the parameters for the direct supervision shall be specified in the facility's policies and procedures.
- The pharmacy technician who performs the checking function must have received specialized and advanced training as prescribed in the policies and procedures of the facility.
- There must be ongoing evaluation of each program that uses pharmacy technicians to check the work of other pharmacy technicians to ensure the quality of patient care and reduce errors.

1. Amend Section 1793.7(b)

This section requires that any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. The amendment would allow general acute care hospitals to establish a program to use of pharmacy technicians in hospital inpatient pharmacies to check the

work of other pharmacy technicians for filling floor stock, ward stock and unit dose cassettes.

2. Add Section 1793.8

This section establishes requirements for general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians filling floor stock, ward stock, and unit dose cassettes.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The Board of Pharmacy has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: None. The regulation permits a pharmacist who was formerly required to check unit dose cassettes to instead be re-deployed to perform clinical services within the hospital. As a result, there will be a shifting of work assignments for some pharmacy technicians and pharmacists that work in hospitals that choose to implement a TCT program.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business. The proposed regulation will only affect general acute care hospitals that choose to implement a TCT program; there is no requirement that the hospitals do so.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address or during the hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 1625 North Market Blvd, Suite N 219, Sacramento, CA 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Web site listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Jan E. Perez
Address:	1625 North Market Blvd, Suite N 219 Sacramento, CA 95834
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E-Mail Address:	jan_perez@dca.ca.gov

The backup contact person is:

Name:	Virginia Herold
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Web site Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.